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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,324	03/10/2005	Khalil Hanna	0513-1142	3505
466	7590	12/20/2007		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER DEAK, LESLIE R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,324

Applicant(s)

HANNA, KHALIL

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 5, 7, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,629,533 to Webb et al in view of US 6,406,453 to Goode et al.

In the specification and figures, Webb discloses the apparatus substantially as claimed by applicant. With regard to claim 1, Webb discloses a lachrymal implant comprising an elongate body 512 with a longitudinal axis and an elliptical top collar 518. The elongate body comprises a first portion with elliptical cross-section adjacent to the collar (see FIGS 6a, 6b, 7) and a second portion or anchoring leg 538 that extends at an oblique angle to the first portion in order to secure the implant within the punctum.

Webb fails to disclose that the second portion of the elongate body comprises two branches. Goode discloses an implant designed to be housed in a body cavity with an elongate portion 16 anchored by two legs 40, 42, that are approximately half the cross-section of the main body 16 and extend outwardly to retain the implant in place (see FIG 1 and accompanying text). It would have been obvious to one having ordinary skill in the art at the time of invention to add the two diverging branches disclosed by Goode to the implant disclosed by Webb in order to retain the implant in place while

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distributing the retaining pressure along a larger area, minimizing potential damage to the surrounding tissue.

With regard to applicant's claim language drawn to the direction in which the branches or legs extend, Webb illustrates a punctum plug with an anchoring leg 538 that extends in two directions from the elongate body 512, wherein the anchoring leg 538 extends along the major axis of the elliptical cross-section of the elongate body (see FIGS 6a, 6b, 7).

With regard to claims 5 and 8, Webb discloses that the collar is an elliptical shape with the major axis parallel to the major axis of the elliptical elongate body (see FIG 6b).

With regard to claim 7, Applicant's recitation of the insertion of the claimed device amounts to a recitation of the function of the device. Apparatus claims cover what the apparatus is, not what it does. See MPEP 2114. In the instant case, Applicant sets forth merely that the branches or legs of the implant are capable of being brought together during insertion into the patient. Goode discloses that the legs or flanges 40, 42 are compressed during insertion of the tube into the patient, and relaxes to regain its expanded shape after insertion (see column 5, lines 60-67, column 6, lines 1-15). Accordingly, it is the position of the Examiner that the apparatus suggested by Webb and Goode is capable of being compressed and inserted as claimed by applicant, meeting the limitations of the claim.

With regard to claim 10, Webb illustrates that the two legs 40, 42, are approximately half the cross-section of the main body 16 (see FIG 1 and accompanying text).

3. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,629,533 to Webb et al in view of US 6,406,453 to Goode et al, further in view of US 5,318,513 to Leib et al.

In the specification and figures, Webb and Goode disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of providing the collar in an offset position relative to the elongate body. Leib discloses and illustrates a lachrymal tube with an elongate body 12 and an offset collar with plug 20/22 (see FIG 2) that allows for retention of the implant along the eyelid 38 without blocking other passages. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the lachrymal implant suggested by Webb and Goode with an offset collar as illustrated by Leib, in order to provide maximum retention while avoiding the blocking of other passages, as illustrated by Leib.

Response to Arguments

4. Applicant's amendments and arguments filed 11 October 2007 have been entered and fully considered.

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5. Applicant's arguments with respect to claims 1, 5, and 6 have been considered but are moot in view of the new ground(s) of rejection. Nonetheless, the Examiner wishes to address Applicant's arguments that are pertinent to the instant rejection.

6. Applicant argues that the geometry of the diverging branches in the claimed invention allows a surgeon to adjust the angular orientation of the apparatus after implantation, which is not taught by the prior art. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, Webb clearly illustrates an anchoring member that extends at an oblique angle in the direction of the major axis of the elliptical elongate body, which allows the implant to be securely implanted within the punctum. Such an arrangement allows for the same maneuvering as argued by Applicant while still providing a secure implantation as taught by Webb, rendering the instantly claimed apparatus unpatentable over the suggestion of the prior art.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

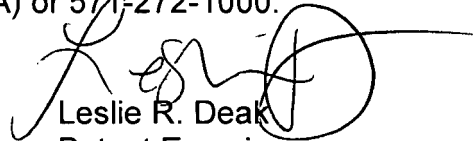
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
10 December 2007